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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,381	12/12/2003	Robert Vincent Faller	7858MRR	9771

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EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,381	FALLER ET AL.	
	Examiner	Art Unit	
	Frederick F. Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 7-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/6/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

Election of Species Requirement

Claims 5-9 are generic to a plurality of disclosed patentably distinct species comprising "additional oral care agents". Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Emelyn Hiland on 3/9/06 a provisional election was made with traverse to prosecute "triclosan" as the ultimate species of "additional oral care agent".

Claims 7-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species there being no allowable generic or linking claim.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "phosphonate group containing polymeric mineral surface-active agent" in claims 1-3 is (apparently) used by the claims to mean phosphonate group containing polymers having unspecified "mineral" elements and surface-active properties, while the accepted meaning is believed (as far as the examiner can determine) to be a "polyphosphonate" which has affinity for tooth surfaces, *i.e.*, which forms a film or coating thereon. See, *e.g.*, page 2, lines 9-12 of the instant specification, and compare with USP 5,032,386 at col. 10, lines 30-51. The term is indefinite because the specification does not clearly redefine it.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaffar et al (USP 5,032,386).

The prior art discloses antiplaque dentifrices (toothpastes, *etc.*) comprising antiplaque agents (*e.g.*, triclosan as disclosed at col. 2, line 48) and polyphosphonates having an affinity for tooth surfaces (col. 6, lines 57 et seq.)¹ Given that bacterial attachment is prevented by formation of a coating of polyphosphonate on the tooth surface (col. 10, lines 30-51) and since acid from oral bacteria is a cause of dental erosion, one would reasonably expect the prior art plaque inhibiting treatments to inherently provide protection from dental erosion as well. Moreover, since fluorine compounds (*e.g.*, sodium fluoride) are included in amounts sufficient to provide up to

¹ Gaffar et al. disclose the specific diphosphonate/acrylate copolymers recited by instant claim 3 through their reference to EP Publication 0321233 at the last line of column 7. USP 4,877,603 is the United States equivalent of that Publication and is cited on the attached 892. (Also attached is a copy of the Derwent Abstract for the European Publication, confirming that equivalency).

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5,000ppm free fluoride ion (col. 12, lines 48-68), one would also expect enhanced "fluoride incorporation into and remineralization of a subject's teeth" to occur as well.²

Obviousness-Type Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

² Note that the instant claims provide no specific frame of reference against which to measure the recited "enchancing" of fluoride incorporation. That being so, the mere addition of fluoride compounds (anti-caries agents that work by increasing remineralization) to the prior art compositions is sufficient to increase fluoride incorporation (and thus remineralization), as compared to the same compositions containing no added fluoride compound.

1) Claims 1-6 and 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 10/737,425 in view of Gaffar et al (USP 5,032,386).

This is a provisional obviousness-type double patenting rejection.

The conflicting claims are drawn to methods for protecting a subject's teeth from erosion comprising administering an oral care composition comprising a polymeric mineral surface active agent which is preferably a copolymer of phosphonate-containing monomers with ethylenically unsaturated monomers thereto, wherein the polymeric mineral surface-active agent is substantive to teeth and deposits a layer thereon that protects the teeth from erosive damage immediately after use and for a period of at least one hour or longer thereafter. The oral care composition may further comprise a source of metal ions (which may be stannous), in an amount sufficient to provide 500 to 20,000ppm metal ions. The methods of the conflicting claims thus differ substantively from the instant claims only insofar as they do not specifically include a fluorine compound, thus "enhancing fluoride incorporation and remineralization."

The secondary reference is discussed in the "Anticipation" section supra, and teaches the incorporation of fluoride compounds as anticaries agents into polyphosphonate-containing antiplaque dentifrices in an amount sufficient to provide up to 5,000ppm fluoride ions. Since the fluoride compound can be stannous fluoride (col. 12, lines 66 and 67), this would also provide up to 5,000 ppm metal ion as well.³

³ Following administration, the dentifrices of the secondary reference form a continuous film over (*i.e.*, they are thus substantive to and deposit a layer on) teeth surfaces. See col. 10, lines 30-51. The prior art films are taught to have a "long retention time on tooth surfaces" (col. 10, lines 46 and 47). Given that the instant claims and the prior art both use polyphosphonates which are substantive to teeth surfaces, one

Accordingly, it would have been obvious to have incorporated stannous fluoride, in an amount sufficient to provide up to 5,000 ppm stannous and fluoride ions into the dentifrices of the conflicting claims, motivated by the desire to improve performance by imparting the anti-caries activity taught by the secondary reference.

2) The examiner notes that the polyphosphates ("condensed phosphorylated polymers") of USP 6,685,920 and USP 6,713,049 (the parent applications of the instant case) were restricted out as patentably distinct species during prosecution of those patents. See, e.g., the first paragraph of p. 4 of Paper 7 in USSN 10/319,108.

Accordingly, the doctrine of obviousness-type double patenting is not seen to apply to the claims of those patents.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

would reasonably expect that "long" would (inherently) be at least one hour in duration as recited by the conflicting claims. Moreover, since bacterial attachment to the tooth surface is prevented (col. 10, lines 34 and 35) and since acid from oral bacteria is a cause of dental erosion, one would reasonably expect the prior art plaque inhibiting treatments to inherently provide protection from dental erosion as well.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614


